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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,998	07/18/2003	Olaf B. Kinstler	0492479-0054 (MGH 2172 US	3557
24280	7590	01/25/2006	EXAMINER ZEMEL, IRINA SOPHIA	
CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			ART UNIT 1711	PAPER NUMBER
DATE MAILED: 01/25/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/622,998	Applicant(s) KINSTLER ET AL.	
	Examiner Irina S. Zemel	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,5,8,9 and 12 is/are allowed.
- 6) ☒ Claim(s) 2,4,6,7,10 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

Claims 2,4,6,7, 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention claims polyacetals derivatives that are derived from controlled lateral oxidative cleavage of dextran which comprises monomeric unit having both R1 and R2 being OH and also units that have R1 or R2 being CH<sub>2</sub>OH (which allegedly result from ring opening without complete cleavage). The applicants stated in their response and in the instant specification that such incomplete cleavage is a result of reacting dextran with periodate in molar ratios of less than 2. No other reaction parameter that may be involved or need to be varied in order to obtain ring opening reaction without complete cleavage are mentioned or described. However, the literature is replete with examples where the reaction of dextran with periodate is carried out with ratios of periodate to dextran of lower than 2, and as result, a polymer containing units that are completely cleaved and units that did not undergo any ring opening reaction is obtained. This is commonly referred to as degree of cleavage (or by any other similar term). See, for example, illustrative example 1 of EP 325 270 to Green Cross Corporation. The reference further expressly states that the amount of periodate used in oxidation reaction is anywhere between 80 mg and up per one gram of dextran, which fully correspond to the disclosed molar ratio of periodate to glucose of less than 2:1.

Therefore, as evidences by the literature, the claimed product that results from controlled cleavage of dextran is NOT obtained by using the disclosed reactant ratios. Therefore, the invention as claimed can not be obtained according to the described procedures and thus, is the inventors has not provide enabling disclosure of how to make the claimed product.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6, 7, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what the recitation "the oxidized product of the polyacetal" refers to, and whether it is the product of claim 2, or the product of claim 2 is further oxidized prior to being conjugated with a protein. Clarification is respectfully requested.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4,6,7, 10 and 11 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) US 6,822,086 to Papisov (hereinafter "Papisov '086"), or

With the assumption that reaction of dextran with periodate with ration if peridate to dextran of less than 2:1 inherently results in t controlled cleavage of dextran, the claimed invention is anticipated by Papisov ' 086 (see intermediate products disclosed in examples 8 and 9 where dextran is reacted with 1.8 moles of peridate and subsequaently reacted with borohydrate). The reference further discloses preparation of protein conjugates (the protins disclosed by the reference correspond to the proteins claimed in the instant application) and therapeutic uses of the conjugates. Since the oxidation reaction is conducted with the amounts of reagents that correspond to the amount that are disclosed in the instant application as governing and resulting in incomplete or controlled oxidation, it is reasonable believed that the polyacetals obtained in the reacton disclosed in the reference fully correspond to the claimed polyacetals.

The burden is shifted to the applicants to provide factual evidence that the disclosed polyacetals and their conjugates are different from those disclosed in the cited art.

The invention as claimed, therefore, is fully disclosed in the cited reference.

***Response to Arguments***

Applicant's arguments with respect to claims 2, 4,6,7, 10 and 11 have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***

Claims 1, 3, 6, 8-9 and 12 allowed.

While lateral oxidative cleavage of dextran with subsequent functionalization of hydroxyl groups is notoriously known in the art, none of the prior art of record discloses polyacetal derivatives that result from oxidation of dextran and that have maleimidocarmoxylic moiety as one of the substituents for one hydroxyl group, their protein conjugates or method of uses of such conjugates.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1711

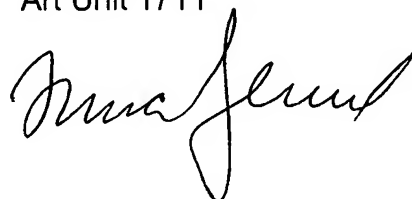
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irina S. Zemel whose telephone number is (571)272-0577. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571)272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ISZ

Irina S. Zemel  
Examiner  
Art Unit 1711

A handwritten signature in black ink, appearing to read 'Irina Zemel', is written over the printed name and title.